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REGULATORY UNIT EVALUATION OF THE BNFL INC. RADIATION PROTECTION PROGRAM FOR DESIGN REVISION 2

October 18, 1999

Office of Safety Regulation of the TWRS-P Contractor

U.S. Department of Energy
Richland Operations Office
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Approved: _____

Date: _____

PREFACE

The U.S. Department of Energy's (DOE) Richland Operations Office (RL) issued a request for proposal in February 1996 for privatized processing of waste as part of the Hanford Tank Waste Remediation System (TWRS) program which in 1999 came under the cognizance of the Office of River Protection (ORP). Offerors were requested to submit proposals for the initial processing of the tank waste at the Hanford Site. Some of this radioactive waste has been stored in large underground storage tanks at the Site since 1944. Currently, approximately 54 million gallons of waste containing approximately 250,000 metric tons of processed chemicals and 215 million curies of radionuclides are being stored in 177 tanks. These caustic wastes are in the form of liquids, slurries, saltcakes, and sludges. The wastes stored in the tanks are defined as high-level radioactive waste (10 CFR Part 50, Appendix F) and hazardous waste (Resource Conservation and Recovery Act).

Under the privatization concept, DOE intends to purchase waste processing services from a contractor-owned, contractor-operated facility through a fixed-price contract. DOE will provide the waste feedstock for processing but maintain ownership of the waste. The contractor must: (a) provide private financing; (b) design the equipment and facility; (c) apply for and receive required permits and licenses; (d) construct the facility and commission its operation; (e) operate the facility to process tank waste according to DOE specifications; and (f) deactivate the facility.

The TWRS Privatization (TWRS-P) Project is divided into two phases, Phase I and Phase II. Phase I is a proof-of-concept/commercial demonstration-scale effort. The objectives of Phase I are to (a) demonstrate the technical and business viability of using privatized contractors to process Hanford tank waste; (b) define and maintain adequate levels of radiological, nuclear, process, and occupational safety; (c) maintain environmental protection and compliance; and (d) substantially reduce life-cycle costs and time required to process the tank waste. The Phase I effort consists of three parts: Part A, Part B-1, and Part B-2.

Part A, which concluded in August 1998, was a twenty-month period to establish technical, operational, regulatory, and financial elements necessary for privatized waste processing services at fixed-unit prices. This included identification by the TWRS-P Contractors and approval by DOE of appropriate safety standards, formulation by the Contractors and approval by DOE of integrated safety management plans, and preparation by the Contractors and evaluation by DOE of initial safety assessments. Of the twenty-month period, sixteen months was for the Contractors to develop the Part A deliverables and four months was for DOE to evaluate the deliverables and determine whether to authorize Contractors to perform Part B. Part A culminated in DOE's authorization on August 24, 1998, of BNFL Inc. to perform Part B-1.

Part B-1 is a twenty-four month period to (a) further the waste processing system design introduced in Part A, (b) revise the technical, operational, regulatory, and financial elements established in Part A, (c) provide firm fixed-unit prices for the waste processing services, and (d) achieve financial closure.

Part B-2 is a sixteen-year period to complete design, construction, and permitting of the privatized facilities; provide waste processing services for representative tank wastes at firm fixed-unit prices; and deactivate the facilities. During Part B-2, approximately 10% by volume (25% by activity) of the total Hanford tank wastes will be processed.

Phase II will be a full-scale production effort. The objectives of Phase II are to implement the lessons learned from Phase I and to process all remaining tank waste into forms suitable for final disposal.

An essential element of the TWRS-P Project is DOE's approach to safety regulation. DOE has specifically defined a regulatory approach and chartered a dedicated Office of Safety Regulation of the TWRS-P Contractor (Regulatory Unit). The DOE aim in proceeding with the safety regulation of the TWRS-P contractor is to establish a regulatory environment that will permit privatization to occur on a timely, predictable, and stable basis. In addition, attention to safety must be consistent with that which would accrue from regulation by external agencies. DOE is patterning its radiological and nuclear safety regulation of the TWRS-P contractor to be consistent with that of the U.S. Nuclear Regulatory Commission (NRC). For industrial hygiene and safety (IH&S), regulation is consistent with that of the Occupational Safety and Health Administration (OSHA).

The RL Manager has responsibility and authority for safety regulation and has assigned this authority to the RL Director of the TWRS-P Regulatory Unit (the Regulatory Official). This regulatory authority is exclusive to the regulation of the TWRS-P contractor. The Regulatory Official is the formal point of execution for safety regulation of the TWRS-P contractor.

The DOE requires the contractor to integrate safety into all facets of work planning and execution. This Integrated Safety Management (ISM) process emphasizes that it is the contractor's direct responsibility for ensuring that safety is an integral part of mission accomplishment. Like the approach taken by the NRC and OSHA, the privatized contractor has primary responsibility for safety. The DOE, through its program, is responsible for ensuring that the contractor establishes and complies with approved safety limits.

The relationship between DOE and the privatized contractor performing work under a fixed-price contract is different than the relationship under traditional Management and Operations (M&O) contracts. For fixed-price contracting to be successful, this different safety relationship with the contractor is accompanied by modified relationships among DOE's internal organizations. For example, the arrangement by which the RL Manager applies regulation to the TWRS-P contractor should be a surrogate for an external regulator (such as the NRC or OSHA) with strong emphasis on independence, reliability, and openness.

Regulation by the RU in no way replaces any legally established external regulatory authority to regulate in accordance with their duly promulgated regulations nor relieves the Contractor from any obligations to comply with such regulations or to be subject to the enforcement practices contained therein.

All documents issued by the Office of Safety Regulation of TWRS-P Contractor are available to the public through the DOE/RL Public Reading Room at the Consolidated Information Center, Room 1012, Richland, Washington. Copies may be purchased for a duplication fee.

Executive Summary

The Office of Safety Regulation of TWRS Privatization Contractors (Regulatory Unit) evaluated the BNFL Inc., "Radiation Protection Program for Design" (RPP), Revision 2. This RPP was submitted on June 2, 1999, in response to changes to regulation 10 CFR 835, "Occupational Radiation Protection." This regulation requires that an updated RPP be submitted to DOE within 180 days of the effective date of any modifications to 10 CFR 835. An amendment to 10 CFR 835 was published in the Federal Register on November 4, 1998, and became effective on December 4, 1998.

The RU performed a detailed review of the BNFL RPP, focusing primarily on changes resulting from the amendment to 10 CFR 835. Because the BNFL RPP is limited to design activities, the amendment to 10 CFR 835 resulted in minimal change to the RPP (i.e., there were five substantive changes to the regulation that affected the RPP). BNFL provided several responses and clarifications during the course of the review. The specifics of the changes to the RPP are provided in the body of this report.

The RU reviewers found that the RPP measures for achieving compliance with 10 CFR 835 met the review criteria established in the RU review guidance documents. As such, the reviewers concluded that the RPP, when properly implemented, will achieve compliance with the regulations.

Based on the results of the review and BNFL's letters in response to RU questions and terminology clarification, the reviewers recommended that the Regulatory Official approve Revision 2 of the BNFL RPP for Design.

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EVALUATION OF THE BNFL RADIATION PROTECTION PROGRAM FOR DESIGN, REVISION 2

1.0 INTRODUCTION

This report documents the Office of Safety Regulation of the TWRS Privatization Contractor (Regulatory Unit) evaluation of the BNFL Inc., "Radiation Protection Program for Design" (RPP), Revision 2. This evaluation was necessary because regulation 10 CFR 835, "Occupational Radiation Protection," requires that an updated RPP be submitted to DOE within 180 days of the effective date of any modifications to 10 CFR 835. An amendment to 10 CFR 835 was published in the Federal Register on November 4, 1998, and became effective on December 4, 1998. The revised RPP was submitted to the RU on June 2, 1999,[1] within the 180 day requirement. BNFL was notified on June 7, 1999, that their submittal contained sufficient information for a detailed review.[2]

The RU performed a detailed review of the BNFL RPP, focusing primarily on changes to the RPP resulting from the amendment to 10 CFR 835. During the review, one set of questions was generated and transmitted to BNFL for resolution in the same submittal on June 7, 1999 (99-RU-0350) noted above. BNFL responded to those questions in letters dated June 15, 1999,[3] and August 9, 1999.[4] The RU also requested clarification of RPP terminology on October 5, 1999,[5] to which BNFL provided clarification on October 12, 1999.[6]

2.0 REVIEW GUIDANCE

The BNFL RPP was evaluated using applicable criteria from review guidance RL/REG-98-11, *Guidance for Review of the TWRS Privatization Contractor Radiation Protection Program Document Required by 10 CFR 835, "Occupational Radiation Protection."* This is an updated version of the original review guide, resulting from the amendment to 10 CFR 835 and from lessons learned during use of the original review guide, where it was found that the numerous individual requirements could more efficiently be captured by grouping them into requirement categories.

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[1] 99-RU-0344, Letter, A. J. Dobson, BNFL Inc., to D. Clark Gibbs, RL "TWRS Privatization Contract No. DE-AC06-96RL13308 – W375 – Submittal of BNFL-TWP-SER-003, Rev. 2," dated June 2, 1999.

[2] 99-RU-0350, Letter, D. C. Gibbs, RL, to M. J. Lawrence, BNFL Inc. "Acceptability Review and First Set of Questions on the BNFL Radiation Protection Program (RPP) for Design, Revision 2," dated June 7, 1999.

[3] 99-RU-0380, Letter, A. J. Dobson, BNFL Inc., to D. C. Gibbs, RL, "TWRS Privatization Contract No. DE-AC06-96RL13308 – W375 – Response to First Set Regulatory Unit Questions on the BNFL Inc. Radiation Protection Program for Design," dated June 15, 1999.

[4] 99-RU-0476, Letter, A. J. Dobson, BNFL, Inc., to D. Clark. Gibbs, DOE/RL, "TWRS Privatization Contract No. DE-AC06-96RL13308 – W375 – Text Revisions in Response to First Set of RU Questions on the BNFL Inc. Radiation Protection Program For Design," dated August 9, 1999.

[5] 00-RU-0003, Letter, D. Clark Gibbs, DOE/RL, to M. J. Lawrence, BNFL, Inc., "Regulatory Unit (RU) Request for Clarification of Terminology Used in the BNFL Inc. Radiation Protection Program (RP) for Design, Revision 2," dated October 5, 1999.

[6] 00-RU-0015, Letter, A. J. Dobson, BNFL, Inc., to D. Clark Gibbs, DOE/RL, "Contract No. DE-AC06-96RL13308 – W375 – Clarification of RPP Terminology," dated October 12, 1999.

This change to the review guide resulted in visible formatting differences between Revision 1 and Revision 2 of the RPP. The reviewers verified that the revised RPP addressed all applicable requirements of the amended 10 CFR 835 and that the updated RPP did not delete elements that were previously approved in Revision 0 of the BNFL RPP.[7] It was also verified that no requirements were dropped or omitted from the revised review guide. The updated review guidance contained a revised applicability matrix (Appendix A, "10 CFR 835 Requirements and Applicability) that contained the new requirements of the amendment to 10 CFR 835.

The measures BNFL identified in the RPP for achieving compliance with 10 CFR 835 were reviewed using the applicable criteria provided in the review guidance. These criteria were:

- Criterion (a): The Contractor's RPP provides reasonable assurance that the activity will be conducted in compliance with the provisions of 10 CFR 835. There is also reasonable assurance that the Contractor can effectively manage and administer the RPP to achieve continued compliance with 10 CFR 835.

- Criterion (b): The content of the RPP conforms to the Contractor's authorization basis documentation.

The review guidance includes attributes for these criteria to assist the reviewers in determining the acceptability of the BNFL proposed measures to achieve compliance with the requirements. In general, there is an expectation that the measures for achieving compliance be identified, complete, implementable, and based on accepted standards (e.g., industry codes and standards, DOE Implementation Guides, U.S. Nuclear Regulatory Commission Regulatory Guides, or international standards). Attributes are not additional requirements.

Meeting the applicable review criteria ensures that the measure being evaluated, when properly implemented, will achieve compliance with 10 CFR 835 and the contract. For some 10 CFR 835 requirements, the language in the regulation is prescriptive. In some cases, a policy statement or commitment in the RPP is an acceptable measure for achieving compliance with that requirement.

3.0 RPP REVIEW AND EVALUATION PROCESS

The review and evaluation of the RPP involved two areas. One was related to changes from the amendment to 10 CFR 835, and the second was due to clarification in the terminology used. The results of the review performed by the RU are presented below.

3.1 AMENDMENTS TO 10 CFR 835

The BNFL RPP is limited to design activities. Because of the RPP's limited scope, the reviewers noted there were only five substantive changes in the amendment to 10 CFR 835 that resulted in changes to the BNFL RPP. The changes in the amendment and the RPP are described below.

[7] 99-RU-0070, Letter, D. Clark Gibbs, RL, to M. J. Bullock, BNFL Inc., "Regulatory Unit (RU) Evaluation of the BNFL Inc. Radiation Protection Program for Design, Revision 0," dated December 2, 1998.

3.1.1 10 CFR 835.3 (e)

Regulatory Change: The addition of subsection (e) now permits a grace period of 30 days for performing periodic internal audits. Specifically, the change states, "For those activities that are required by §§ 835.102, 835.901(e), 835.1202(a), and 835.1202(b), the time interval to conduct these activities may be extended by a period not to exceed 30 days to accommodate scheduling needs."

Proposed RPP Change: BNFL identified in their applicability matrix (Appendix A) that Section 5.2 contained the measures for assuring compliance with 10 CFR 835.3(e). Specifically, Section 5.2 was changed from requiring an audit of all function elements of the radiation protection program within a 36-month timeframe to allowing a 30-day grace period beyond the 36-month timeframe.

Reviewer Determination: The reviewers noted Section 5.2 was revised to address the requirements of 10 CFR 835.3(e) as they relate to design. This was determined acceptable compliance with 10 CFR 835.3(e).

3.1.2 10 CFR 835.103

Regulatory Change: The addition of subsection 835.103 addresses the "Education, training, and skills" of the individuals responsible for ensuring compliance with 10 CFR 835.

Proposed RPP Change: The BNFL RPP was changed to include a requirement that states, "Individuals responsible for developing and implementing measures necessary for ensuring compliance with the requirements of this part shall have the appropriate education, training, and skills to discharge these responsibilities." BNFL identified in their applicability matrix (Appendix A) that Section 5.0 contained the measures for assuring compliance with 10 CFR 835.103.

Reviewer Determination: The reviewers noted that Section 5.0 contains the compliance statement but does not include measures for achieving compliance as required by 10 CFR 835.101(f). Question No. 2, of the June 7, 1999 RU transmittal, requested an explanation of what measures BNFL would use to achieve compliance with 10 CFR 835.103.

Contractor Response: BNFL responded by stating that Section 5.4 of the RPP contained the measures for assuring compliance with 10 CFR 835.103.

Final Reviewer Determination: The reviewers noted that Section 5.4 references the Quality Assurance Program and Implementation Plan (QAPIP), Chapter 2.0, "Personnel Training and Qualification." The reviewers found that Chapter 2.0 of the QAPIP does provide the measures for achieving compliance with 10 CFR 835.103 as required by 10 CFR 835.101(f). Thus, the revision to the RPP and the BNFL response to question No. 2 were determined to identify an acceptable measure for compliance with 10 CFR 835.103.

3.1.3 10 CFR 835.104

Regulatory Change: The addition of section 10 CFR 835.104 requires written procedures. The requirement states, "Written procedures shall be developed and implemented as necessary to ensure compliance with this part, commensurate with the radiological hazards created by the activity and consistent with the education, training, and skills of the individuals exposed to those hazards."

Proposed RPP Change: The BNFL RPP was changed to add this requirement in Section 5.5.6. BNFL identified in their applicability matrix (Appendix A) that Section 5.5.6 contained the measures for assuring compliance with 10 CFR 835.104.

Reviewer Determination: The reviewers noted that Section 5.5.6 contained a compliance statement that was a restatement of the requirement, being in effect a policy statement. Without identifying additional measures, it was unclear whether BNFL intended to apply this requirement to design activities. Question No. 1 of the June 7, 1999, transmittal requested that BNFL explain what measures would be used to apply this requirement to design activities.

Contractor Response: BNFL responded by committing to rewrite the statement in Section 5.5.6 to clarify this. The revised statement in response to question No. 1 was changed from merely having procedures and codes of practice for actual physical radiological hazards to having procedures and codes of practice for the radiological hazards associated with the activity.

Final Reviewer Determination: The RU reviewers determined the revised statement in Section 5.5.6 of the BNFL RPP clarifying that BNFL intends to apply the requirement to all activities, including design, was acceptable.

In addition, Section 5.5.6 further validates BNFL's commitment to the requirements in 10 CFR 835.104 because it provides a list of ALARA process elements that will be documented through appropriate procedures and codes of practice. The RU reviewers determined the list had not been changed from Revision 1 of the RPP. The RU reviewers found this list consistent with guidance provided in the *Implementation Guide for Use With 10 CFR 835, Occupational Radiation Protection*, "Occupational ALARA Program," and therefore identifying acceptable measures for compliance with 10 CFR 835.104.

The RU reviewers also noted that the third paragraph in Section 5.0 of the BNFL RPP had been rewritten to address 10 CFR 835.104. Section 5.0 now states, "In accordance with QAP Chapter 5.0, BNFL Inc. processes, actions, and program components for ensuring compliance with 10 CFR 835 will be implemented through documented, management-approved procedures and codes of practice." The review of Chapter 5.0 of the QAPIP found adequate measures for complying with the regulatory requirements of 10 CFR 835.104. Thus, the revised statement in Section 5.0 of the RPP also adequately addresses the requirements of 10 CFR 835.104.

3.1.4 10 CFR 835.1001

Regulatory Change: There were wording changes to 10 CFR 835.1001. The revised 10 CFR 835.1001 changed "facility and equipment design" to "physical design features" and deleted "procedural requirements" from being listed as a separate administrative control.

Proposed RPP Change: BNFL identified in their applicability matrix (Appendix A) that Sections 5.5.10.1, 5.5.10.2, and 5.5.10.3 contained the measures for assuring compliance with 10 CFR 835.1001. The sections were revised to address the amendment to 10 CFR 835.1001. These changes were as follows:

- Section 5.5.10.1

  Previous wording: "The primary methods used to minimize radiation exposure in controlled areas shall be physical design features (e.g., confinement, ventilation, remote handling, shielding)."

  New wording: "The primary methods used to minimize radiation exposure in controlled areas shall be physical design features (e.g., confinement, ventilation, remote handling, and shielding)."

- Section 5.5.10.2

  Previous wording: "Administrative controls and procedural requirements shall be employed only as supplemental methods to control radiation exposure."

  New wording: "Administrative controls shall be employed only as supplemental methods to control radiation exposure."

- Section 5.5.10.3

  Previous wording: "For specific activities where use of physical design features are demonstrated to be impractical, administrative controls and procedural requirements shall be used to maintain radiation exposures ALARA."

  New wording: "For specific activities where use of physical design features is demonstrated to be impractical, administrative controls shall be used to maintain radiation exposures ALARA."

Reviewer Determination: These revisions were determined acceptable for compliance with 10 CFR 835.1001.

3.1.5 10 CFR 835.1003

Regulatory Change: There were wording changes and clarifications to the requirements of 10 CFR 835.1003. Some of the rewording was similar to the changes in 10 CFR 835.1001 (e.g.,

"administrative control procedures" was changed to "administrative controls" so administrative controls are not limited to procedures).

Proposed RPP Change: BNFL identified in their applicability matrix (Appendix A) that Section 5.5.10.8 contained the measures for assuring compliance with 10 CFR 835.1003.

Reviewer Determination: The reviewers noted that Section 5.5.10.8 was revised to accommodate the revisions to 10 CFR 835.1003(a) and (b), however, it was noted that Section 5.5.10.8 continued to limit BNFL to administrative control procedures. Question No. 3 of the June 7, 1999, RU transmittal requested that BNFL clarify the methods BNFL plans to use to implement workplace controls.

Contractor Response: BNFL responded by committing to delete the limitation on using administrative control procedures to implement workplace controls. Specifically, the change to Section 5.5.10.8 of the RPP was as follows:

- Section 5.5.10.8

  Previous wording: "During routine operations, a combination of design features and administrative control procedures shall provide…"

  New wording: "During routine operations, the combination of physical design features and administrative controls shall provide…."

Final Reviewer Determination: The revision to Section 5.5.10.8 and the response to question No. 3 were determined acceptable for of compliance with 10 CFR 835.1003 because the changes addressed the requirements, provided measures for achieving compliance, and removed the ambiguity of workplace controls.

3.2 TERMINOLOGY CLARIFICATION

In addition to the above changes required by the amendment to 10 CFR 835, the reviewers found the BNFL RPP contained a number of terms that warranted clarification. These terms were: technically competent, safety case, and identification of whether engineering systems were either deterministic or probabilistic.

Proposed RPP Changes: Specifically, the changes made to the RPP were as follows:

- Section 5.5.1, bullet 3

  Previous wording: "Ensure that technically competent personnel are responsible for implementing and overseeing the Radiological Controls Program."

  New wording: "Ensure that personnel responsible for developing and implementing measures necessary for ensuring compliance with the requirements of 10 CFR 835 shall have the appropriate education, training, and skills to discharge these responsibilities."

- Section 5.5.8.1, last bullet, sentence 2

  Previous wording: "In particular, note that prospective dose data from safety cases and design assessments often are conservative estimates and should be used with care."

  New wording: "In particular, note that prospective dose data from safety analyses and design assessments often are conservative estimates and should be used with care."

- Section 5.5.9.2, bullet 2, sentence 2

  Previous wording: "Engineered safety features may be either deterministic (ensuring by their design that safety limits are not exceeded) or probabilistic (low failure probability presenting low risk)."

  New wording: "Engineered safety features may be deterministic (ensuring by their design that safety limits are not exceeded) or probabilistic (low failure probability presenting low risk)."

Reviewer Determination: The RU reviewers determined that BNFL's proposed changes to Revision 2 of the RPP appropriately clarified these terms, did not decrease the effectiveness of the RPP, and did not affect the plans, schedules, and measures for achieving compliance with the applicable requirements of 10 CFR 835.

4.0 CONCLUSIONS AND RECOMMENDATIONS

The RU performed a detailed review of Revision 2 of the BNFL RPP, focusing primarily on changes to the RPP resulting from the amendment to 10 CFR 835. Because the BNFL RPP is limited to design activities, the amendment to 10 CFR 835 resulted in minimal change to the RPP (i.e., there were five substantive changes to the regulation that affected the BNFL RPP).

The reviewers found that Revision 2 of the BNFL RPP addressed all the applicable requirements of 10 CFR 835 and contained acceptable measures for achieving compliance with the applicable requirements of 10 CFR 835. The reviewers determined that this RPP met the review criteria established in the RU review guidance document. As such, the reviewers concluded that, if properly implemented, Revision 2 of the BNFL RPP, when revised in accordance with commitments in the BNFL response letters of June 15, 1999, August 9, 1999, and October 12, 1999, will achieve compliance with 10 CFR 835.

Based on the results of the review and BNFL's letters addressing the RU reviewer's questions, the reviewers recommended that the Regulatory Official approve Revision 2 of the BNFL RPP.

5.0 ACRONYMS

ALARA	As Low as is Reasonably Achievable
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
RL	Richland Operations Office
ICRP	International Commission on Radiological Protection
QAP	Quality Assurance Program
RPP	Radiation Protection Program
RU	Regulatory Unit
TWRS-P	Tank Waste Remediation System Privatization

6.0 REFERENCES

Code of Federal Regulations, 10 CFR Part 835, Occupational Radiation Protection, U.S. Department of Energy.

G-10 CFR 835/B2- Rev. 1, *Implementation Guide For Use With Title 10, Code of Federal Regulations, Part 835, Occupational Radiation Protection*, "Occupational ALARA Program," 1994.

RL/REG-98-11, *Guidance for Review of the TRWS Privatization Contractor Radiation Protection Program Document Required By 10 CFR 835, Occupational Radiation Protection*, Rev. 1, 1999, Richland, Washington.